

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 112, are respectfully requested.

Status

Applicants' Request for Continued Examination ("RCE") has been granted and Applicants' submission dated July 15, 2003, has been entered. See *Official Action mailed September 29, 2003, Page 2*.

As is correctly reflected in the Office Action Summary, Claims 1-18 and 20-92 are pending. Claims 5-7, 30, 44-46, 49, and 91 have been withdrawn from consideration. Claims 1-4, 8-18, 20-29, 31-43, 47, 48, 50-90, and 92 stand rejected.

Summary of Amendments

By the foregoing amendments, Claims 12, 14, 27, 33, 34, and 38 were amended to correct minor and typographical errors. Support for these amendments may be found at least in the original corresponding claims. Accordingly, no new matter has been added.

Also by the foregoing amendments, Claims 51-92 have been cancelled without prejudice or disclaimer to Applicants filing one or more continuing applications directed to the subject matter previously presented therein.

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Personal Interview Conducted March 25, 2004

Applicants wish to thank Examiner Wells and Supervisor Padmanabhan for the courtesies extended to the undersigned and Mr. Brian P. O'Shaughnessy (Registration No. 32,747) during the personal interview ("Interview") conducted on March 25, 2004. During the Interview, the pending claims, the cited publications, and possible claim amendments were discussed, as indicated on the Interview Summary sheet.

Rejection Under 35 U.S.C. § 112, Second Paragraph — Indefiniteness

Claims 1-4, 8-18, 20-29, 31-43, 47-48, 50-90, and 92 were rejected under 35 U.S.C. § 112, Second Paragraph, as purportedly indefinite. See *Official Action mailed September 29, 2003, Pages 2-3*. This rejection is respectfully traversed.

Not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, Claims 59 and 73 have been cancelled and Claims 12 and 27 have been amended maintain consistency in formatting within the Markush groups. Applicants believe this renders moot the rejections set forth in part (i) on Page 3 of the Official Action mailed September 29, 2003.

Similarly, not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, Claim 61 was cancelled and Claim 14 was amended to recite fatty alkyl ethers. Applicants believe this renders moot the rejections set forth in part (ii) on Page 3 of the Official Action mailed September 29, 2003.

With regard to the rejections set forth in part (iii) on Page 3 of the Official Action mailed September 29, 2003, Applicants have amended Claim 33 to correct a

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typographical error and, therefore, to recite "0.1% - 10%," as set forth on Page 14, Paragraph 0080 of the Specification. Applicants believe this renders moot the foregoing rejections.

Again, not to acquiesce in the Examiner's rejection, but solely to facilitate prosecution, Claims 79-81 were cancelled and Claim 34 was amended to specify that the O/W emulsion contained in Claim 31 further comprises at least one pro-penetrating agent. Applicants believe this renders moot the rejections set forth in part (iv) on Page 3 of the Official Action mailed September 29, 2003.

Finally, with respect to the rejection set forth in part (v) on Page 3 of the Official Action mailed September 29, 2003, Applicants respectfully traverse this rejection and request withdrawal thereof. Applicants respectfully direct the Examiner's attention to Page 14, Paragraph 0082, of the Specification, where specific cellulose derivatives are set forth.

In view of the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, Second Paragraph, indefiniteness rejections to remaining Claims 1-4, 8-18, 20-29, 31-43, 47-48, and 50.

Rejection Under 35 U.S.C. § 103(a) – Lochhead in View of the Handbook

Claims 1-4, 8-10, 15-18, 20-29, 40-43, 47-48, 50-57, 62-75, 85-90, and 92 were rejected under 35 U.S.C. § 103(a) as purportedly obvious over European Patent Application 0 268 164 to Lochhead *et al.* ("Lochhead") in view of the Handbook of Cosmetic Science and Technology ("Handbook"). See Official Action mailed September 29, 2003, Pages 4-6. This rejection is respectfully traversed.

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To establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. See *M.P.E.P.* § 2142. Applicants respectfully assert that even if one were motivated to combine Lochhead with the Handbook, a notion Applicants do not concede, such a combination would not establish a *prima facie* case of obviousness of the rejected claims because the cited publications do not disclose or suggest all of the claim limitations.

Specifically, independent Claims 1, 41, [49,] and 50 specify that the biologically active agent (A) is in micronized particulate state and is non-solubilized in said emulsion, wherein at least 80%, numerically, of said micronized particles have diameters ranging from 1 to 10 μm , and at least 50%, also numerically, of said micronized particles have diameters of less than 5 μm . The size of the particles disclosed in Lochhead is directed to the size of the dispersed phase (oil) of the emulsion, whereas in Applicants' invention, the size of the particles is directed to the micronized and non-solubilized biologically active agent particles independently of the size of the oily droplets of the emulsion. The Handbook does not cure the deficiencies of Lochhead, as this, too, does not refer to Applicants' micronized, non-solubilized biologically active agent particles, but to the emulsion particle size.

Because the combination of Lochhead and the Handbook fails to disclose or suggest at least the size of the micronized, non-solubilized biologically active agent particles of Applicants' invention, Applicants submit a *prima facie* case of

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obviousness has not, and cannot, be made out. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of remaining Claims 1-4, 8-10, 15-18, 20-29, 40-43, 47-48, and 50.

Rejection Under 35 U.S.C. § 103(a) – Lochhead in View of the Handbook in Further View of Pisson

Claims 11-12, 37-39, 58-59, and 82-84 were rejected under 35 U.S.C. § 103(a) as purportedly obvious over Lochhead in view of the Handbook in further view of U.S. Patent No. 5,882,633 to Pisson *et al.* ("Pisson"). See *Official Action mailed September 29, 2003, Pages 7-8*. This rejection is respectfully traversed.

As explained above, Applicants maintain that the combination of Lochhead and the Handbook fail to establish a *prima facie* case of obviousness against any of the pending claims. Pisson does not cure the deficiencies of Lochhead and the Handbook. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of Claims 11-12 and 37-39 over Lochhead in view of the Handbook in further view of Pisson.

Rejection Under 35 U.S.C. § 103(a) – Lochhead in View of the Handbook in Further View of Pisson in Further View of Kaplan

Claims 13-14 and 60-61 were rejected under 35 U.S.C. § 103(a) as allegedly obvious over Lochhead in view of the Handbook in further view of Pisson and further in view of U.S. Patent No. 5,916,543 to Kaplan *et al.* ("Kaplan"). See *Official Action mailed September 29, 2003, Page 8*. This rejection is respectfully traversed.

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As explained above, Applicants maintain that the combination of Lochhead and the Handbook fail to establish a *prima facie* case of obviousness against any of the pending claims. As with Pisson, Kaplan does not cure the deficiencies of Lochhead and the Handbook. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of Claims 13-14 over Lochhead in view of the Handbook in further view of Pisson and Kaplan.

Rejection Under 35 U.S.C. § 103(a) – Lochhead in View of the Handbook in Further View of Kim

Claims 31-36 and 76-81 were rejected under 35 U.S.C. § 103(a) as purportedly obvious over Lochhead in view of the Handbook in further view of U.S. Patent No. 5,980,939 to Kim *et al.* ("Kim"). See Official Action mailed September 29, 2003, Pages 8-9. This rejection is respectfully traversed.

As explained above, Applicants maintain that the combination of Lochhead and the Handbook fail to establish a *prima facie* case of obviousness against any of the pending claims. Kim does not cure the deficiencies of Lochhead and the Handbook. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of Claims 31-36 over Lochhead in view of the Handbook in further view of Kim.


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CONCLUSION

From the foregoing, further and favorable consideration in the form of a Notice of Allowance is respectfully requested and earnestly solicited.

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
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Date: March 29, 2004

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REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Status

Applicants' Request for Continued Examination ("RCE") has been granted and Applicants' submission dated July 15, 2003, has been entered. See *Official Action mailed September 29, 2003, Page 2*.

As is correctly reflected in the Office Action Summary, Claims 1-18 and 20-92 are pending. Claims 5-7, 30, 44-46, 49, and 91 have been withdrawn from consideration. Claims 1-4, 8-18, 20-29, 31-43, 47, 48, 50-90, and 92 stand rejected.

Summary of Supplemental Amendment

The instant Supplemental Amendment and Reply assumes entry of the Amendment and Reply filed March 29, 2004. By the foregoing Supplemental Amendment and Reply, Claims 93 and 94 have been added to round out the scope of protection to which Applicants are entitled. Support for Claim 93 may be found throughout the Specification and at least at original Claim 1. Support for Claim 94 may be found throughout the Specification and at least at original Claim 1 and Paragraphs 0013 and 0026. Accordingly, no new matter has been added.

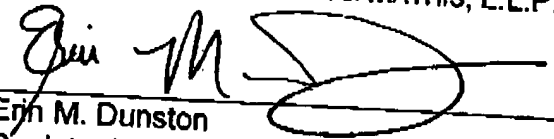
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CONCLUSION

From the foregoing, further and favorable consideration in the form of a Notice of Allowance is respectfully requested and earnestly solicited.

In the event that there are any questions relating to this Supplemental Amendment and Reply, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
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